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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,593	10/25/2001	Douglas A. Collins	COP1008US	6800

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,593

Applicant(s)

COLLINS ET AL

Examiner

Traviss C. McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8 and 11-31 is/are pending in the application.
- 4a) Of the above claim(s) 15-28 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,11,12,14 and 31 is/are rejected.
- 7) ☒ Claim(s) 13 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The Amendment filed May 20, 2005 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

The specification has been amended.

Claims 1, 5, 7-8, 11-18, 20-21, and 28 have been amended.

Claims 29-31 have been added

Claims 4, 9, and 10 have been cancelled.

Remarks drawn to rejections of Office Action mailed December 15, 2004 include:

Specification objection: which has been overcome by applicant's amendments and has been withdrawn.

Claim objections: which have been overcome by applicant's amendments and have been withdrawn.

112 2nd paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

102(e) rejection: which has been overcome by applicant's amendments and has been withdrawn.

Claims 15-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As set forth in the previous Office Action, election was made **without** traverse in the reply filed on

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September 2, 2004. Additionally, newly added claim 30 is withdrawn as it depends from withdrawn claim 16.

An action on the merits of claims 1-3, 5-8, 11-14, 29, and 31 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Objections

Claim 13 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). In the instant case, claim 13 optionally depends from claim 6, which depends from claim 5, which depends from any of claims 1-3. Accordingly, the claim 13 not been further treated on the merits.

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Who the composition is intended to be given to is of no patentable import to the composition as claimed.

Claim 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

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claim(s) in independent form. Who the composition is intended to be given to is of no patentable import to the composition as claimed.

Additionally, claim 29 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). In the instant case, claim 29 depends from claim 13, which optionally depends from claim 6, which depends from claim 5, which depends from any of claims 1-3. Accordingly, since claim 13 is not being treated on the merits as set forth supra, claim 29 has also not been further treated on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7, 11-12, and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 17-18, 21-24 and 57 of U.S. Patent No. 6,806,363. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to cobalamin compounds linked to therapeutic agents via linkers which are optionally peptides or amino acids. It is noted

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that the '363 patent requires a B-10 molecule to be attached additionally, however, since the claims of the instant application use open language, the B-10 molecule is not delimited from being incorporated into the instantly claimed compounds. Moreover, the instant application requires that one of various positions on the cobalamin molecule be "not as it is found in natural vitamin B₁₂", and since the '363 patent requires B-10, that meets the limitations as B-10 is not found in natural vitamin B₁₂. Additionally, both applications claim compositions comprising the same. It is noted that the previous amendment changed the charge of the cobalt molecule to "+" instead of "+3" and the '363 patent has a charge of "+3". However, the examiner believes that the '363 patent may be improperly labeled with the "+3" charge, as they state their compounds are those of formula I of figure 1 (see column 6 lines 15-21). Additionally, the '363 patent states that figure 1 depicts the structure of cobalamin (see column 7, lines 53-55). It is noted cobalamin has a "+" charge and not a "+3" charge as indicated, and as applicants have evidenced by amending the instant application. Even if it were not so, the examiner believes it is obvious to use variously charged molecules, as well as various metals within the center of the porphyrin ring as it is well known in the art that the placement of various metals such as cobalt, nickel, palladium, platinum, rhodium, zinc, and lithium, into the center of the corrin ring has not presented any problems (as evidenced by US 6,613,305 – column 2, lines 50-52).

Claims 1-3, 5-8, 11-12, and 14 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-11 of U.S. Patent No. 6,838,073 in view of Collins et al. (US 6,613,305). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to

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cobalamin compounds linked to therapeutic agents via linkers which are optionally peptides or amino acids. It is noted that the instant application is drawn to a molecule with a "Co⁺" as the metal in the porphyrin ring and the '073 patent has a "Cu⁺⁶" metal. However, it is obvious to use variously charged molecules, as well as various metals within the center of the porphyrin ring as it is well known in the art that the placement of various metals such as cobalt, nickel, palladium, platinum, rhodium, zinc, and lithium, into the center of the corrin ring has not presented any problems (as evidenced by US 6,613,305 – column 2, lines 50-52).

Claims 1-3, 5-8, 11-12, and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-111 of copending Application No. 10/859,865.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to cobalamin compounds linked to therapeutic agents via linkers which are optionally peptides or amino acids. It is noted that the instant application is drawn to a molecule with a "Co⁺" as the metal in the porphyrin ring and the '865 patent has a "CO₄" moiety indicated. However, the examiner believes the CO₄ moiety of the '865 application to be a typographical error, as this molecule would not appear to be able to be made due to the drastic valence problems that would be formed. The examiner believes the moiety intended was a "Co⁺" moiety, as this is the correct moiety for cobalamin, which the '865 patent is drawn to. The '865 application is also drawn to chemotherapeutic agents being conjugated to the cobalamin compounds, wherein the instant application is drawn to "therapeutic agents", however, it is noted that the instant application also limits the therapeutic agents to

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chemotherapeutic agents (see claim 2 for example). As such, both applications are seen to be clearly overlapping wherein they are drawn to cobalamin compounds coupled to chemotherapeutic agents via a linker which is optionally a peptide or amino acid.

This is a provisional obviousness-type double patenting rejection as the claims of the '865 application have not yet been patented.

Claim Rejections - 35 USC § 112

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim intends to limit -L-T to one of various poly(amino acid) residue, however the claim is silent to what is intended for T. If applicants added the phrase "comprising one or more T" to the claim as they did to claim 5 in the previous amendment, wherein the claim would read: "is independently a poly (amino acid) residue comprising one or more T selected from the group consisting of ...", this would be seen to render the instant rejection moot.

Claim 31 is rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants failed to define what is intended for the variables for Z^1 , Z^3 , Z^4 , Z^5 , Z^7 , or Z^8 .

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

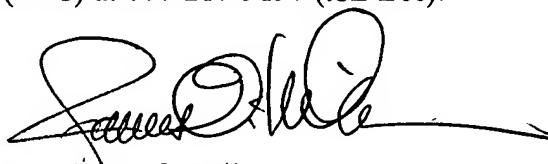
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
August 4, 2005



James O. Wilson
Supervisory Patent Examiner
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